REMARKS

Claims 1-5 are pending in the application and have been rejected. Claim 1 has been amended, and new claim 6 and 7 have been added. Reexamination and reconsideration of the claims, as amended, are respectfully requested.

Objection to Drawings under 37 CFR. 1.83(a)

In the Office Action the Examiner objected to the drawings under 37 CFR 1.83(a) stating the drawings must show every feature of the invention specified in the claims and that "the coating of the radiopaque material over the stainless steel stent which varies in thickness over the axial length must be shown or the feature(s) cancelled from the claim(s). Applicant respectfully directs the Examiner's attention to FIGS. 21A through 21E and specification pages 21 through 22, of the application as originally filed, and submits that these figures meet the requirements of 37 CFR 1.83(a). For that reason, Applicant requests the withdrawal of this objection.

Claim Rejection under 35 U.S.C. §102

In the Office Action, the Examiner rejected claims 1, 4, and 5 under 35 U.S.C. §102(e) as being anticipated by Lashinski et al (USPN 6,071,296).

More particularly, the Examiner referencing column 5, lines 63-66 and column 6, lines 1-5, noted that "Lashinski et al discloses a stent made of radiopaque material wherein the radiopaque material is thicker near the ends of the cylindrical frame than over the midsection."

Lashinski et al is directed to a stent comprising an expandable, generally tubular body portion in which one or both ends of the stent are provided with a generally rounded, smooth radiused portion that forms a bulbous protrusion out of the plane of the circumference of the stent (Abstract). In describing the material for forming the stent, the specification describes that "[t]he stent and radii are preferably formed from radiopaque materials. Since there typically is more material in the end regions of the stents of the present invention compared to the stents of the prior art, the increased amount of

radiopaque material at the ends of the stent are more clearly outlined during deployment, thereby assisting accurate placement of the stent." This description is more particularly directed to those embodiments (such as FIG. 5) wherein more material 54 is added in the regions of apex 52 of the stent (Column 4, lines 60-63) or by thickening the stent (column 5, lines 15-17), increasing the profile of the apex 52.

"Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration." *W.L. Gore & Associates v. Garlock, Inc.*, 220 USPQ 303, 313 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984).

In contrast to Lashinski et al, claim 1 as presently amended, is directed to a prosthesis comprising a cylindrical frame having a distal end, a proximal end, and a midsection disposed between the proximal and distal ends. The frame comprises a radiopaque material which varies in thickness over the midsection of the cylindrical frame so that the radiopacity of the frame varies correspondingly.

Lashinski et al does not disclose a prosthesis comprising a radiopaque material varying in thickness along the portion between its two ends. The stent of Lashinski et al is made of a radiopaque material which by virtue of a greater thickness at the distal ends has a greater radiopacity at the ends.

Applicant submits that claim 1, as amended, and claims 2- 4 which depend directly or indirectly therefrom, are not anticipated by or obvious in view of Lashinski et al and that they are patently distinguishable over the same.

In contrast to Lashinski et al, claim 5, is directed to a prosthesis comprising "a cylindrical frame having a distal end, a proximal end, and a midsection therebetween, wherein the cylindrical frame is modified to be radiopaque at each end but to remain sufficiently radiolucent over the midsection to permit fluoroscopic viewing of a blood vessel lumen in which the prosthesis is implanted."

Lashinski et al does not disclose a prosthesis comprising a relatively radiolucent midsection. The entire stent of Lashinski et al is made of a radiopaque material which by virtue of a greater thickness at the distal ends has a greater radiopacity

at the ends. It is quite different to require that the midsection be radiolucent (as set forth in claim 5) so that the ends are more radiopaque (as taught by Lashinski).

Applicant submits that claim 5 is not anticipated by or obvious in view of Lashinski et al and requests withdrawal of this rejection and the allowance of claim 5.

Claim Rejection under 35 U.S.C. §103

The Examiner rejected claims 2 and 3 under 35 U.S.C. §103 as being unpatentable over Lashinski et al (USPN 6,071,296), in view of Callol et al (USPN 6,174,329).

In rejecting the claims, Examiner stated that "Lashinski et al discloses the invention substantially as claimed, ... [h]owever Lashinski et al does not disclose a frame made of stainless steel and a coating made of gold, platinum, etc."

Assuming arguendo that Claim 1 were not patentably distinguishable over Lashinski et al, Applicant submits that Claims 2 and 3 are nevertheless patentable over Lashinski et al alone or in combination with Callol et al.

"In proceedings before the Patent and Trademark Office, the Examiner bears the burden of establishing a prima facie case of obviousness based upon the prior art '[The Examiner] can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references.'" *In re Fritch*, 23 USPQ 2d 1780, 1783 (Fed. Cir. 1992) quoting *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ 2d 1596, 1598 (Fed. Cir. 1988).

Applicant respectfully submits that a prima facie case of obviousness has not been established. There is no objective teaching for changing the material of Lashinski et al to that of the Callol et al. The stent of Lashinski et al is entirely made of radiopaque material with the objective only being to provide a less traumatic device. The stent of Callol et al is made of two different material, a sufficiently radiopaque stent and a thin radiopaque layer of material.

Assuming arguendo that a prima facie case of obviousness has been made, Applicant respectfully submits that the combination of the two reference is improper.

'A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant. The degree of teaching away will of course depend on the particular facts; in general, a reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant. See United States v. Adams, 383 U.S. 39, 52, 148 USPQ 479, 484 (1966) ("known disadvantages in old devices which would naturally discourage the search for new inventions may be taken into account in determining obviousness").' *In re Gurley*, 31 USPQ 2d 1130, 1131 (Fed. Cir. 1994).

Callol et al teaches away from using a variable thickness radiopaque material as for example noted on Column 5, lines 1-3, stating that "[t]hus, the thickness of the radiopaque layer should be uniform and in the preferred thickness ranges ..., where it will be implanted, the diameter of struts 15, and the like."

Additionally, Callol et al teaches away from using the radiopaque material on those portions of the stent that are curved, as for example noted on column 5, lines 21-24, stating that "... while stent portion 31, which is curved, is not covered by a radiopaque layer." The stent of Lashinski et al has the higher radiopacity at the radii having a generally rounded (i.e., curved) radius (column 3, lines 18-19).

For all of the reasons stated above, Applicant submits that claims 2 and 3 are patentably distinguishable over Lashinski et al alone or in combination with Callol et al, and requests the withdrawal of the rejection and allowance of the Claims 2 and 3.

Additional Remarks

Applicant has added news claims 6 and 7 and submits that they are directed to patentable subject matter and that it is patentably distinguishable over

Lashinski et al alone or in combination with Callol et al. Applicant respectfully requests the allowance of newly added claims 6 and 7.

Attached hereto is a marked-up version of the changes made to the specification and Claims by the current amendment. The attached pages is captioned "Version With Markings To Show Changes Made."

The Applicant believes that the pending claims are directed to patentable subject matter. Consideration and an early allowance thereof are earnestly solicited.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION (pg. 21 – beginning w/line 8):

[Referring to Figs. 22A-22E, a method for plating a typical prosthesis made from stainless steel with radiopaque material, such as gold, platinum, platinum/iridium, tungsten, tantalum, or the like, will now be described. The method of the present invention creates a prosthesis with a coating of radiopaque material having an axially selective thickness. It should be understood, however, that the method is not limited to thickness variations in the axial direction and may be used to create an unlimited number of thickness configurations. Preferably, the prosthesis is entirely covered with a layer of radiopaque material while having thicker deposits of the same or other materials near its ends and having thinner deposits over the remainder, typically midsection, of the device. When the coating material is gold, the thickness near the ends 111 and 113 is preferably between 0.0003 and 0.0009 inches, more preferably between 0.0004 and 0.0007 inches. Thicknesses over the remainder of the prosthesis may be in the range of 0.0002 to 0.0004 inches. The thicker deposits near the ends of the prosthesis make the ends more radiopaque and thus create a stronger image, facilitating the positioning of the prosthesis in its desired location. The middle area 304 is also preferably coated so as to be more radiopaque than the uncoated material under the fluoroscope, but permitting sufficient radiolucency so that the lumen inside the prosthesis may still be inspected fluoroscopically. Alternatively, the middle area 304 may be left uncoated while only the ends of the prosthesis remain coated to achieve an optimal axial radiopacity distribution. Visualization through this middle area 304 may be crucial for observing future restenosis or hyperplasia within the prosthesis. Coating the entire prosthesis at a uniform thickness using the optimal thickness applied to the ends would likely obscure such visualization. Having an axially selective coating customizes the prosthesis to the desired task. It should be understood that the

present method may be used to add materials of a variety of thicknesses to a prosthesis.]

Referring to Figs. 21A-21E, a method for plating a typical prosthesis made from stainless steel with radiopaque material, such as gold, platinum, platinum/iridium, tungsten, tantalum, or the like, will now be described. The method of the present invention creates a prosthesis with a coating of radiopaque material having an axially selective thickness. It should be understood, however, that the method is not limited to thickness variations in the axial direction and may be used to create an unlimited number of thickness configurations. Preferably, the prosthesis is entirely covered with a layer of radiopaque material while having thicker deposits of the same or other materials near its ends and having thinner deposits over the remainder, typically midsection, of the device. When the coating material is gold, the thickness near the ends 111 and 113 is preferably between 0.0003 and 0.0009 inches, more preferably between 0.0004 and 0.0007 inches. Thicknesses over the remainder of the prosthesis may be in the range of 0.0002 to 0.0004 inches. The thicker deposits near the ends of the prosthesis make the ends more radiopaque and thus create a stronger image, facilitating the positioning of the prosthesis in its desired location. The middle area 304 is also preferably coated so as to be more radiopaque than the uncoated material under the fluoroscope, but permitting sufficient radiolucency so that the lumen inside the prosthesis may still be inspected fluoroscopically. Alternatively, the middle area 304 may be left uncoated while only the ends of the prosthesis remain coated to achieve an optimal axial radiopacity distribution. Visualization through this middle area 304 may be crucial for observing future restenosis or hyperplasia within the prosthesis. Coating the entire prosthesis at a uniform thickness using the optimal thickness applied to the ends would likely obscure such visualization. Having an axially selective coating customizes the prosthesis to the desired task. It should be understood that the present method may be used to add materials of a variety of thicknesses to a prosthesis.

IN THE CLAIMS:

1. (Amended) A radially expansible luminal prosthesis comprising:

a cylindrical frame having a distal end, a proximal end, a midsection therebetween, and an outer surface for insertion into a body lumen, wherein said frame comprises a radiopaque material which varies in thickness over an axial length of the midsection of the cylindrical frame, so that the radiopacity of the frame varies correspondingly.

APPENDIX A

COMPLETE SET OF PENDING CLAIMS

WHAT IS CLAIMED IS:

1. (Amended) A radially expansible luminal prosthesis comprising:

a cylindrical frame having a distal end, a proximal end, a midsection therebetween, and an outer surface for insertion into a body lumen, wherein said frame comprises a radiopaque material which varies in thickness over an axial length of the midsection of the cylindrical frame, so that the radiopacity of the frame varies correspondingly.

2. (As filed) A radially expansible luminal prosthesis as in claim 1, wherein the cylindrical frame comprises stainless steel and a radiopaque material is coated over the stainless steel.

3. (As filed) A radially expansible luminal prosthesis as in claim 2, wherein the radiopaque material is selected from the group consisting of gold, platinum, platinum/iridium, tungsten, and tantalum.

4. (As filed) A radially expansible luminal prosthesis as in any of claims 1 to 3, wherein the radiopaque material is thicker near the ends of the cylindrical frame than over the midsection.

5. (As filed) An improved radially expansible luminal prosthesis of the type comprising a cylindrical frame having a distal end, a proximal end, and a midsection therebetween, wherein the cylindrical frame is modified to be radiopaque at each end but to remain sufficiently radiolucent over the midsection to permit fluoroscopic viewing of a blood vessel lumen in which the prosthesis is implanted.

6. (New) A radially expansible luminal prosthesis comprising:

a cylindrical frame having distal and proximal ends, and comprising a radiopaque material having varied thickness along a length disposed between the proximal and distal ends, the frame having varying radiopacity along the length.

7. (New) A radially expansible luminal prosthesis comprising:

a cylindrical frame having a distal end, a proximal end, and an outer surface for insertion into a body lumen, wherein said frame comprises a radiopaque material which varies in thickness over an axial length of the cylindrical frame disposed between the proximal and distal ends, so that the radiopacity of the frame varies correspondingly.